supply of skilled personnel. A Task Force under the chairmanship of Union Secretary (Health and Family Welfare) has been constituted to deliberate upon the issue of setting up the proposed National Council. The Task Force shall submit its report to the Ministry by 31st July, 2009.

Human clinical trials

216. PROF. ALKA BALRAM KSHATRIYA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has mandated all human clinical trials being done in the country to be registered with the Indian Council of Medical Research (ICMR);

(b) if so, whether the offenders of unethical trials and those who violate the norms would be punished;

(c) if so, the details thereof; and

(d) the details of unethical human clinical trials came to the notice of Government during the past few months and action taken by Government thereon?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Prior to 17th November 2008, registration of clinical trial was voluntary. For all the clinical trials, permission of which were granted between 17th November 2008 to 14th June 2009, applicants were advised to get the trials registered at Indian Council of Medical Research (ICMR) registry at *www.ctri.in.*. However for all clinical trials permitted on or after 15th June 2009, applicants are being informed that it is now mandatory to register the trial at the said ICMR site before enrolling first patient in the study.

(b) and (c) Under Rule 122DB of Drugs and Cosmetics Rules, if any applicant fails to comply with any of the conditions of clinical trial permission, Drugs Controller General (India) can suspend or cancel the permission.

(d) The inspection of one of the sites of a clinical trial by a team constituted by Central Drugs Standard Control Organisation (CDSCO), revealed various Good Clinical Practices (GCP) violations. Therefore, the concerned investigator, sponsor and monitor were issued warning letters asking them to take corrective actions to prevent such violations in future. The clinical trial remained suspended at all the twelve sites from 06.11.2008 to 22.04.2009. The sponsor submitted various corrective actions taken to ensure GCP compliance. CDSCO scrutinized the same and decided to revoke the suspension on 23.04.2009 from all the sites except the inspected site. Further monitor and investigator of the inspected site also submitted details of corrective actions taken by them, based on which the suspension from the inspected site was also revoked on 02.06.2009.